

# PATENT COOPERATION TREATY



## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



|  |  |  |  |  |
|--|--|--|--|--|
| Applicant's or agent's file reference<br>100792-1 WO   |  | <b>FOR FURTHER ACTION</b>  |  | See Form PCT/IPEA/416                        |
| International application No.<br>PCT/GB2004/001934   |  | International filing date (day/month/year)<br>04.05.2004   |  | Priority date (day/month/year)<br>06.05.2003 |
| International Patent Classification (IPC) or national classification and IPC<br>A61K31/47, A61K31/4709, A61P25/18, A61P25/26, A61P25/28  |  |  |  |  |
| Applicant<br>ASTRAZENECA AB et al.   |  |  |  |  |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |  |  |  |  |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>  |  |  |  |  |
| Date of submission of the demand<br><br>09.02.2005   |  | Date of completion of this report<br><br>24.03.2005  |  |  |
| Name and mailing address of the international preliminary examining authority:<br> European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465  |  | Authorized Officer<br>Telephone No. +49 89 2399-  |  |  |

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/001934

---

**Box No. I Basis of the report**

---

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-23 as originally filed

**Claims, Numbers**

1-24 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/001934

---

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

---

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-6 (partial)

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-6 (partial) are so unclear that no meaningful opinion could be formed (*specify*):

**see separate sheet**

☒ the claims, or said claims Nos. 1-6 (partial) are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 1-5 (IA)

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/001934

---

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

---

**1. Statement**

|                               |             |          |
|-------------------------------|-------------|----------|
| Novelty (N)                   | Yes: Claims | 10       |
|                               | No: Claims  | 1-9      |
| Inventive step (IS)           | Yes: Claims | 10       |
|                               | No: Claims  | 1-9      |
| Industrial applicability (IA) | Yes: Claims | 3,4,6-10 |
|                               | No: Claims  |          |

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/GB2004/001934

**1. Re Item III.**

Claims 1, 2, 5, relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT). However, although not required under the provisions of the PCT, an opinion will be given with respect to novelty and inventive step.

Furthermore, due to the expression "conditions in which modulation of the alfa-7 nicotinic receptor is beneficial", present claims 1-6 relate to an extremely large number of possible diseases. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the diseases claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the diseases explicitly mentioned in claim 2. The present opinion is limited to the subject matter which has been searched.

**2. Re Item V.**

The following document have been cited in the search report. Where reference is made to them, the following numbering is used; unless otherwise indicated, reference is made to the passages mentioned in the Search Report:

- D1 :** WO 98/34111 A (TREGA BIOSCIENCES INC) 6 August 1998
- D2:** DATABASE REGISTRY CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; 1998, XP002291222
- D3:** US-A-3 631 050 (ELSLAGER EDWARD F ET AL) 28 December 1971
- D4:** DATABASE CHEMCATS CHEMICAL ABSTRACT SERVICE, COLUMBUS OHIO, US; Accession Number: 2001:2073353 23 April 2003, XP002291223
- D5:** DATABASE CHEMCATS CHEMICAL ABSTRACT, OHIO; 2002, AN: 1940051- 1940080; XP002291224

**2.1 Novelty**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1,2, 3, 4, 5, 6, 7, 8, 9, is not new in the sense of Article

33(2) PCT.

**D1** discloses pharmaceutical compositions comprising compounds falling in the definition of the compounds of formula I in claim 1, 3 and 6, and their use for the treatment of pain. In view of this prior art, the subject matter of claims 1-6 is not new.

**D3** discloses pharmaceutical compositions comprising compounds falling in the definition of the compounds of formula I in claim 3. In view of this prior art, the subject matter of claims 3 is not new.

**D4** discloses a compound falling among the list of claim 9. In view of this disclosure claims 7, 8, 9 are not new.

**D5** discloses a number of compounds falling in the definition of claims 7 and 8. In view of this prior art, the subject matter of claims 7 and 8 is not new.

## **2.2 Inventive step (Art.33(3) PCT)**

The claimed subject matter which is new appears to involve an inventive step.

## **2.3 Industrial application**

Claims 1,2,5 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).